IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:

SCARIA et al. Examiner: Dave T. Nguyen

Serial No.: 10/057,620 Group Art Unit: 1632

Filing Date: October 25, 2001

For: **METHODS FOR TREATING BLOOD COAGULATION DISORDERS**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313 on March 29, 2005

Printed name: Taryn Antalek Signature of person mailing correspondence

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).

☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.

☒ Before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees required pursuant to 37 C.F.R. § § 1.17(p) or 1.17(i)(1).

This Information Disclosure Statement is filed:

☐ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever comes first, and the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for the fee ($180.00) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

This Information Disclosure Statement is filed:

☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee ($180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 more than three months prior to the filing of this Information Disclosure Statement.

II. Copies of the Cited Items:

☒ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.

☐ Copies of only the following items listed on the attached Form PTO-1449 are not enclosed:

☐ Copies of those items which are marked with an asterisk (*) in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. _____

filed _____ and relied upon in this application for an earlier filing date under 35 U.S.C. § 120. See 37 C.F.R. § 1.98(d).

☐ Copies of those items which are marked with an asterisk (**) in the attached Form PTO-1449 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

III. Concise Explanation of Relevance:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;

2. a representation that a search has been made, other than as described above; or

3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in §1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. **07-1074** for any additional fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted,

3/29/05
Date

By: _____
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PTO/SB/08a (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/057,620
Filing Date	October 25, 2001
First Named Inventor	SCARIA
Art Unit	1632
Examiner Name	Dave T. Nguyen
Attorney Docket Number	5046US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-4,784,950	11-15-1998	ZymoGenetics, Inc.	
	2	US-			
	3	US-			
	4	US-			
	5	US-			
	6	US-			
	7	US-			
	8	US-			
	9	US-			
	10	US-			
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	14	US-			
	15	US-			
	16	US-			
	17	US-			
	18	US-			
	19	US-			
	20	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] - Number[4] - Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	21	EP 0 775 750	05-28-1997	Immuno AG		
	22	WO 97/20043	06-05-1997	Zymogenetics, Inc.		
	23	WO 00/23116	04-27-2000	Avigen, Inc.		
	24	WO 01/70763	09-27-2001	The Children's Hospital of Philadelphia		
	25					
	26					
	27					
	28					
	29					

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	10/057,620
Filing Date	October 25, 2001
First Named Inventor	SCARIA
Art Unit	1632
Examiner Name	Dave T. Nguyen
Attorney Docket Number	5046US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	31	MILLER, G. et al., "Expression of factor VII by muscle cells in vitro and in vivo following direct gene transfer: modelling gene therapy for haemophilia", Gene Therapy, Volume 2, Number 10: pps. 736-742, 1 December 1995	
	32	SHAH, A.M. et al., "Manipulation of the membrane binding site of vitamin K-dependent proteins: Enchanced biolgoical function of human factor VII", Proceedings of the National Academy of Sciences, USA, Volume 95, Number 8: pps. 4229-4234, 14 April 1998	
	33	ARKIN S. et al., "Activated recombinant human coagulation factor VII therapy for intracranial hemorrhage in patients with hemophilia A or B with inhibitors: Results of the NovoSeven emergency-use program", Database Biosis Online, Biosciences Information Service, Database Accession No. PREV1999900229958 XP002228408 abstract & HAEMOSTASIS, Volume 28, Number 2: pps. 93-98, March 1998	
	34	ROMAN, Drews et al., "Proteolytic maturation of protein C upon engineering the mouse mammary gland to express furin", Database BIOSIS Online, Biosciences Information Service, Database Accession No. PREV199698601105 XP 002228409 abstract & PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, Volume 92, Number 23: pps. 10462-10466, 1995	
	35	HART, C E et al., "Characterization of a cDNA coding for human factor VII", Database Medline Online, Database Accession No. NLM3486420 XP002228410 abstract & PROC NATL ACAD SCI, USA, Volume 83, pps 2412-2416, 1986	
	36	PARIS, MARGARITIS et al., "Long-term expression of activated FVII in vivo following AAV-mediated liver gene transfer: Implications for treatment with continuous infusion of recombinant activated FVII", Database BIOSIS Online, Biosciences Information Service, Database Accession No. PREV200200220527 XP 002228411 abstract * BLOOD, Volume 98, No. 11, Part 1, pps. 696a, 16 November 2001	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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